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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,177	02/18/2004	Rafail Zubok	SPINE 3.0-455 CIP CONT I	1815
530 7590 04/29/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER WOODALL, NICHOLAS W	
			ART UNIT 3733	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/781,177	Applicant(s) ZUBOK ET AL.	
	Examiner Nicholas Woodall	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/05/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 01/11/2008.

Information Disclosure Statement

2. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b)**. Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 7-9 and 16-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification of the current application does not provide a written description directed to a substantially circular-shaped head including a first substantially circular-shaped surface and a second substantially circular-shaped surface spaced apart from each other. The drawings

include support for the added limitations, so the amended claim limitations are not new matter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-5 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (U.S. Patent 7,063,725) in view of Willinger (U.S. Patent 6,213,055).

Regarding claim 1, Foley discloses a device comprising a shaft having a handle at a proximal end and a head disposed at a distal end of the shaft. The head includes a first surface and a second surface that are spaced apart by a distance as discussed and shown in the previous office action. Regarding claim 2, Foley discloses a device wherein the first surface has a generally oval footprint area and the second surface also includes an area. Regarding claim 3, Foley discloses a device wherein at least one of the first surface includes a substantially convex area or the second surface includes a substantially flat area. Regarding claim 4, Foley discloses a device wherein at least one of the first surface is tapered towards the distal end or the second surface is tapered towards the distal end. Regarding claim 10, Foley discloses a set of devices wherein each device comprises a shaft having a handle at a proximal end and a head disposed at a distal end of the shaft. The head includes a first surface and a second surface that are spaced apart. Foley further discloses the set of devices have head portions that

differ in size (column 18 lines 42-55). Regarding claims 11 and 12, Foley discloses a set of devices wherein the heads of the devices differ in thickness by about 1 mm (column 7 lines 3-7). Regarding claim 13, Foley discloses a device wherein a square area of at least one of the trials differs from a head square area of at least one of the trials.

Regarding claim 14, Foley discloses a set of devices wherein at least one of a head thickness differs from a head thickness if at least one other of the trials and at least two heads of substantially the same head thickness have differing respective head square areas. Foley discloses a set of devices wherein the thickness of the heads of the devices have differing thicknesses. Regarding claim 15, Foley discloses a set of devices further including one or more disc replacement devices (column 18 lines 42-55). Foley fails to disclose a device further comprising at least one rib extending transversely away from the shaft and longitudinally along the shaft substantially to the head. Willinger teaches a device comprising a shaft having a handle at a proximal end and a head disposed at a distal end of the shaft further comprising at least one rib extending transversely away from the shaft and longitudinally along the shaft substantially to the head. Thus it would have been obvious to one having ordinary skill in the art to apply the technique of adding at least one rib extending transversely away from the shaft and longitudinally along the shaft substantially to the head as taught in Willinger to improve the device of Foley for the predictable result of forming a strong reinforcement and interconnection between the shaft and the head. *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (2007).

Regarding claim 5, the combination of Foley and Willinger disclose a device wherein the head portion of the device includes a first surface and a second surface as discussed above. The combination of Foley and Willinger disclose the first and second surfaces of the head portion can be tapered at any angle. The combination of Foley and Willinger fail to disclose the first surface of the head portion to be tapered at an angle of about 5 degrees and the second surface of the head portion to be tapered at an angle of about 4 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Foley modified by Willinger wherein the head portion of the device with a first surface at an angle of about 5 degrees and with a second surface at an angle of about 4 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

7. Claims 7-9 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (U.S. Patent 7,063,725) in view of Michelson (U.S. Publication 2003/0135279) and Hanson (U.S. Publication 2003/0028197).

Regarding claims 7-9, Foley discloses a device comprising a shaft having a handle at a proximal end and a head disposed at a distal end of the shaft. The head includes a first surface and a second surface that are spaced apart by a distance as discussed and shown in the previous office action. Foley fails to disclose the invention further comprising a stop member and the head being substantially circular-shaped and the first and second surfaces being substantially circular-shaped, i.e. a disc shaped head. Michelson teaches a device including a shaft with a handle and a head portion

further including a stop member (claim 7) that extends transversely at an anterior end of the head portion (claims 8 and 9). Hanson teaches a device comprising a rasp/trial, wherein the head is substantially circular-shaped and wherein a first and second surface are spaced apart and substantially circular-shaped in order to provide a trial that matches the shape of an implant (page 6 paragraph 104 and page 7 paragraphs 105 and 106). It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the technique of adding a stop member that extends transversely at an anterior end of the head portion as taught in Michelson to improve the device of Foley for the predictable result of preventing over penetration of the device and it would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Foley wherein the head is substantially circular-shaped and the first and second surfaces are substantially circular-shaped in view of Hanson in order to provide a trial that matches the shape of an implant.

Regarding claim 16, the combination of Foley, Michelson, and Hanson disclose a device as discussed above inherently capable of being used by a method comprising the steps of inserting a first of the trials into one of the intervertebral disc spaces to facilitate at least some distraction of the vertebral bones in a direction along a longitudinal axis of the spinal column and inserting a second of the trials into the intervertebral disc space to facilitate at least some further distraction of the vertebral bones along the longitudinal axis, where the second trial has a larger head thickness, measured substantially from the first surface to the second surface, than that of the first

trial, where in the insertion steps include contacting the stop member with a portion of one of the vertebral bones. Regarding claim 17, the combination of Foley, Michelson, and Hanson disclose a device as discussed above inherently capable of being used by a method as discussed above further comprising the step of levering the handle of at least one of the first and second trials to facilitate the distraction of the vertebral bones. Regarding claim 18, the combination of Foley, Michelson, and Hanson disclose a device as discussed above inherently capable of being used by a method as discussed above further comprising the step repeating the insertion of further trials having larger and larger head thicknesses to facilitate the distraction of the vertebral bones to a target distance. Regarding claim 19, the combination of Foley, Michelson, and Hanson disclose a device as discussed above inherently capable of being used by a method as discussed above wherein the target distance is one that substantially maximizes the intervertebral space while substantially preserving annulus and ligaments associated with the vertebral bones. Regarding claim 20, the combination of Foley, Michelson, and Hanson disclose a device as discussed above inherently capable of being used by a method as discussed above further comprising the step of inserting an intervertebral disc replacement device into the intervertebral space after it has been distracted to the target distance.

Response to Arguments

8. Applicant's arguments filed 01/11/2008 have been fully considered but they are not persuasive. The applicant's argument that Foley and Willinger are non-analogous art is not persuasive. The examiner would like to note, "The examiner must determine

what is "analogous prior art" for the purpose of analyzing the obviousness of the subject matter at issue. *Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed. " KSR International Co. v. Teleflex Inc., 550 U.S. ___, ___, 82 USPQ2d 1385, 1397 (2007). Thus a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole." (see MPEP 2141.01(a) I). Willinger teaches a device comprising a shaft and a head portion, wherein the shaft includes a rib portion connected to the head portion to reinforce the connection between the shaft and the head portions of the device. Foley discloses a device comprising a head portion and a shaft. It would have been obvious to one having ordinary skill in the art to manufacture Foley wherein the shaft further includes a rib connected to the head portion as taught by Willinger to reinforce the connection between the head portion and the shaft of the device. The examiner believes taking Willinger's of reinforcing the connection between a head portion and a shaft and adding the teaching to Foley's device is logical and obvious to one having ordinary skill in the art. The rejections for claims 1-5 and 10-15 have not been changed and are reproduced from the previous office action. The examiner has presented new grounds of rejection for claims 7-9 and 16-20 as necessitated by the applicant's amendments to those claims. This office action is **FINAL**.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733